

REMARKS

I. Status of the Application

Claims 1 and 3-27 are pending in the application. New claims 28 and 29 have been added. Claims 1, 3, 8 and 10 have been amended. Claim 7 has been canceled without prejudice to the filing of any appropriate continuation applications. Claims 1 and 3-16 stand rejected under 35 U.S.C. § 102(b) as anticipated by each of Nakagawa et al., U.S. Patent No. 3,901,819, Jones, U.S. Patent No. 3,956,159, Green et al., U.S. Patent No. 4,772,412, Barnes, U.S. Patent No. 4,981,606, and Kong et al., U.S. Patent No. 5,505,740. Claims 17-27 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Gaffar et al., U.S. Patent No. 5,648,064, or McLaughlin, U.S. Patent No. 6,108,850, taken with any one of each of Nakagawa et al., Jones, Green et al., Barnes, and Sanderson et al., U.S. Patent No. 5,458,802. Claims 19-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,221,341. Claims 19-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-12 of U.S. Patent No. 6,221,341 in view of Nakagawa et al., Jones, Green et al., Barnes and/or Sanderson et al. Claims 19-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, and 7 of U.S. Patent No. 5,922,307 in view of Nakagawa et al., Jones, Green et al., Barnes and/or Sanderson et al. Claims 1, 3-5, 7, 8, 11, 12, 17 and 19-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, 7, and 9 of U.S. Patent No. 5,908,614 in view of Nakagawa et al., Jones, Green et al., Barnes and/or Sanderson et al.

Applicant has amended the claims to more clearly define and distinctly characterize Applicant's novel invention. Support for the amendments can be found in the specification and

the claims as originally filed. Claim 1 has been amended to require an orally acceptable source of peroxide and an orally acceptable acetic acid ester of glycerin. Support for this amendment can be found in the specification at least at page 7 lines 7-9, page 11, line 19 to page 12, line 3, and in the preamble of claim 1. Support for chewing gum and dental floss recited in new claims 28 and 29 can be found in the specification at least at page 13, lines 6-8. Claims 3 and 8 have been amended to properly depend from claim 1. Claim 10 has been amended to correct an inadvertent typographical error. The amendments presented herein add no new matter. Attached hereto is a marked-up version of the changes made to the claims captioned "Version Of Amendments With Markings To Show Changes Made."

Applicant respectfully requests entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

Also, Applicant submits herewith a Terminal Disclaimer to obviate the Examiner's double patenting rejections of claims 19-27 over U.S. Patent No. 6,221,341.

II. Nakagawa et al., Jones, Green et al., Barnes and Kong et al. are Nonanalogous Art

At the outset, Applicant notes that each of Nakagawa et al., Jones, Green et al., Barnes and Kong et al. is directed to the use of certain compositions to bleach or otherwise wash clothing or hard surfaces. Applicant acknowledges the Examiner's understanding at page 3 that the references do not teach oral care compositions for whitening teeth, however, the Examiner believes that the claims include only a statement of intended use as to oral care compositions, and accordingly, the claimed compositions are not distinguishable from the compositions to bleach or otherwise wash clothing or hard surfaces identified in the cited patents.

While Applicant disagrees with the Examiner's belief, Applicant has amended the claims to clarify that the claimed composition is an orally acceptable, tooth whitening peroxyacetic acid generating mixture. Applicant respectfully submits that the cited patents are directed to nonanalogous art and therefore, are not properly citable against the present invention. The Federal Circuit has adopted a "two-step test" for determining whether references are within the appropriate scope of prior art. *In re Deminski*, 796 F.2d 436 (Fed. Cir. 1986). First, the reference has to be "within the field of the inventor's endeavor." If it is not, it must be determined "whether the reference is reasonably pertinent to the particular problem with which the inventor was involved." Id. "[A] basis for determining whether art is analogous ...is to look at whether it deals with a problem similar to that being addressed by the inventor." *Union Carbide Corp. v. American Can Co.*, 724 F.2d 1567 (Fed. Cir. 1984), *aff'd* 724 F.2d 1567 (Fed. Cir. 1984).

The cited patents fail each prong of the two-step test: (1) they are not within the field of Applicant's endeavor, and (2) they are not reasonably pertinent to the particular problem with which the Applicant is involved. Regarding the first prong, it cannot be credibly argued that the cited patents disclosing compositions for bleaching or otherwise cleaning clothing or hard surfaces is in the same field of endeavor as orally acceptable tooth bleaching compositions. Cleaning laundry is a different field of endeavor from oral care products.

Regarding the second prong, Applicant's claimed tooth bleaching composition and the laundry bleaching compositions of the cited patents address vastly different problems in disparate fields. Applicant's composition addresses the removal of stains from teeth within the oral cavity. As a result, Applicant's composition is orally acceptable and whitens teeth without harmful effects to the oral cavity. The compositions of the cited patents are not concerned with

orally acceptable formulations or harmful effects to the oral cavity because none of the cited patents intend or otherwise suggest that it would be useful to put the compositions into his or her mouth. One would not be led by the cited patents to place the compositions disclosed therein on any tissue inside of the oral cavity. The problems addressed by the cited patents is clean clothing without, perhaps, damage to the clothing itself. This problem is very different from the problems faced by Applicant, namely to whiten teeth without harmful effects to human tissue.

Given the dissimilarity of the fields of endeavor and the dissimilarity of the particular problems, the cited patents cannot fairly be considered analogous art and the rejection is improper. *See In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992) (“the combination of elements from non-analogous sources, in a manner that reconstructs the applicant’s invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness”).

III. Claims 1 and 3-16 Are Novel Over Nakagawa et al., Jones, Green et al., Barnes and Kong et al.

Claims 1 and 3-16 stand rejected under 35 U.S.C. § 102(b) over Nakagawa et al., Jones, Green et al., Barnes and Kong et al. Applicant respectfully traverses this rejection.

Applicant has amended the claims to clarify that the claimed composition is an orally acceptable, tooth whitening peroxyacetic acid generating mixture.

Nakagawa et al. fails to disclose each and every element of claim 1, namely an orally acceptable, tooth whitening peroxyacetic acid generating mixture. Nakagawa et al. concerns an activating composition for intensifying the bleaching activity of an inorganic peroxide bleaching agent at low temperatures. There is nothing in Nakagawa et al. to indicate that its composition is orally acceptable. Such would be counterintuitive for a laundry cleaning composition. Given the

above deficiencies of Nakagawa et al., Applicant contends that the rejections of claims 1 and 3-16 on the basis of Nakagawa et al. are improper and should be withdrawn.

Jones discloses bleach solutions that contain as essential ingredients t-butyl alcohol, ethylene diacetate, and glycerol triacetate. Jones fails to disclose each and every element of claim 1, namely an orally acceptable, tooth whitening peroxyacetic acid generating mixture. There is nothing in Jones to indicate that its composition is orally acceptable, especially given the presence of t-butyl alcohol in their compositions. See col. 2 lines 30-50. Oral acceptability would be counterintuitive for a laundry cleaning composition. Given the above deficiencies of Jones, Applicant contends that the rejections of claims 1 and 3-16 on the basis of Jones are improper and should be withdrawn.

Green et al. fails to disclose each and every element of claim 1, namely an orally acceptable, tooth whitening peroxyacetic acid generating mixture. Green et al. concerns a new grade of sodium perborate anhydrous and its use in detergent compositions. There is nothing in Green et al. to indicate that its composition is orally acceptable, especially in view of the disclosure that the sodium perborate anhydrous includes by-products of an undefined nature as a result of the heat-drying process. See col. 3 lines 1-25. Oral acceptability would be counterintuitive for a laundry cleaning composition. Given the above deficiencies of Green, Applicant contends that the rejections of claims 1 and 3-16 on the basis of Green are improper and should be withdrawn.

Barnes fails to disclose each and every element of claim 1, namely an orally acceptable, tooth whitening peroxyacetic acid generating mixture. Barnes is directed to liquid cleaning products for washing stained fabrics, dishes, cutlery, surgical instruments and the like. There is nothing in Barnes to indicate that its compositions are orally acceptable. Given the above

deficiencies of Barnes, Applicant contends that the rejections of claims 1 and 3-16 on the basis of Barnes are improper and should be withdrawn.

Kong et al. fails to disclose each and every element of claim 1, namely an orally acceptable, tooth whitening peroxyacetic acid generating mixture or an anhydrous carrier. Kong et al. concerns a bleaching product and method of removing soils from fabrics. Kong et al. does not disclose an anhydrous carrier in which a source of peroxide and an acetic acid ester of glycerin are dispersed. The glycerol triacetate of Table III was added, along with lipase K-10, to an aqueous solution of sodium bicarbonate (namely TIDE detergent), see column 18, lines 25-60, and the encapsulated, coated dry tablets that the Examiner referred to in the rejection encapsulate only the delayed-release acidification agent, see column 11, lines 33-63. The acids discussed at this section fall under the heading “Delayed Acidification or Acid Release Agent,” and include acetic acid, citric acid, boric acid, malonic acid, etc., see column 10, lines 38-50. As such, these acids are clearly not sources of peroxide or acetic acid ester of glycerin and therefore do not anticipate the present claims.

Further, there is nothing in Kong et al. to indicate that the compositions are orally acceptable. Such would be counterintuitive for a laundry cleaning composition. Given the above deficiencies of Kong et al., Applicant contends that the rejections of claims 1 and 3-16 on the basis of Kong et al. are improper and should be withdrawn.

IV. Claims 17-27 are Patentable Over Gaffar et al., or McLaughlin taken with any one of each of Nakagawa et al., Jones, Green et al., Barnes, and Sanderson et al.

Claims 17-27 are rejected under 35 U.S.C. § 103(a) as unpatentable over Gaffar et al. or McLaughlin, taken with any one of each of Nakagawa et al., Jones, Green et al., Barnes, and Sanderson et al. Applicant respectfully traverses the Examiner’s rejections. At the outset,

Nakagawa et al., Jones, Green et al., and Barnes are nonanalogous art for the reasons stated earlier. Sanderson et al., also directed to detergent compositions, is also nonanalogous art. Accordingly, the Examiner has not presented a *prima facie* case of obviousness.

Gaffar et al., US Patent No. 5,648,064, discloses two-component whitening dentifrice compositions in which a first component contains a peroxygen compound and a second component contains a manganese coordination complex compound, such as manganese gluconate, which activates the peroxygen compound to release active oxygen. See Abstract. Gaffar does not teach or suggest a peroxyacetic acid generating mixture or composition for producing peroxyacetic acid as required by claims 17 and 18, respectively. Since the invention of Gaffar et al. does not seek to generate peroxyacetic acid, one of skill in the art would not look to any reference to modify Gaffar et al. to include triacetin to generate peroxyacetic acid. Also, contrary to the Examiner's position, one of skill in the art would not look to the laundry cleaning art to identify acetic acid esters of glycerin.

Nor does Gaffar et al. teach or suggest a method for whitening teeth comprising the combining or mixing of a hydrogen peroxide precursor, glyceryl triacetate, and water so as to generate peroxyacetic acid as required by claims 19-21. Gaffar et al. further does not teach or suggest a method for cosmetically treating teeth comprising applying a source of labile acetyl groups onto the surface of a tooth, allowing the source of labile acetyl groups to penetrate into the tooth, and applying a source of peroxide onto the surface of the tooth and allowing it to react with the labile acetyl groups to generate a peroxyacid, as required by claims 22-27.

McLaughlin, U.S. Patent No. 6,108,850, describes a composition that contains a bleaching compound and a catalytic agent. The catalytic agent is described as a compound or molecule which accelerates the whitening action of the bleaching compound without being

consumed in the reaction, with activated charcoal, platinum and platinum salts, copper and copper salts, palladium and palladium salts, and silver and silver salts given as examples. There is no acetic acid ester of glycerin in the invention of McLaughlin, and in fact McLaughlin teaches away from the use of an acetic acid ester of glycerin by teaching the use of a catalyst that is not consumed in the reaction. In the present invention, the acetic acid ester of glycerin degrades, in the presence of peroxide, into acetic acid (after first converting to peroxyacetic acid), water, and other degradation products. Specification at page 12, lines 4-9. One skilled in the art would not be motivated to combine art that teaches the use of an acetic acid ester of glycerin with McLaughlin.

V. **Double Patenting Rejections of Claims 19-27 over U.S. Patent No. 6,221,341.**

Claims 19 to 27 stand rejected under the judicially created doctrine of double patenting over claims 1 and 2 of U.S. Patent No. 6,221,341 as improperly extending the “right to exclude.” Claims 19 to 27 also stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 and 2 of U.S. Patent No. 6,221,341.

Applicant submits herewith a Terminal Disclaimer to obviate these rejections, accompanied by the proper fee. Applicant respectfully submits that the Terminal Disclaimer renders the double patenting rejections over U.S. Patent No. moot and requests that these rejections be reconsidered and withdrawn.

VI. Claims 1, 3, 4, 5, 7, 8, 11, 12, 17, and 19-27 are Patentable over U.S. Patent Nos. 6,221,341, 5,922,307 and 5,908,614 in view of Nakagawa et al., Jones, Green et al., Barnes, and/or Sanderson et al. and therefore do not result in Obviousness-Type Double Patenting

The Examiner has rejected claims 19-27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-12 of U.S. Patent No. 6,221,341 and claims 1, 4 and 7 of U.S. Patent No. 5,922,307, each in view of Nakagawa et al., Jones, Green et al., Barnes, and/or Sanderson et al. Claims 1, 3, 4, 5, 7, 8, 11, 12, 17, and 19-27 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, 7, and 9 of U.S. Patent no. 5,908,614 in view of Nakagawa et al., Jones, Green et al., Barnes, and/or Sanderson et al. Applicant respectfully traverses these rejections.

The Examiner opined in each of these rejections that, in view of any of Nakagawa et al., Jones, Green et al., Barnes, and/or Sanderson et al., it would be obvious to anyone of ordinary skill in the art that the addition of glyceryl triacetate (“GTA”) to expectedly boost the peroxide or peroxide precursor would not only be motivated, but there would also be a reasonable likelihood of success (emphasis in the original). However, as noted above, Nakagawa et al., Jones, Green et al., Barnes, and Sanderson et al. are nonanalogous art and so cannot form the basis for a *prima facie* case of obviousness. Further, in all but Nakagawa et al., the GTA is merely included as a non-aqueous solvent or as a component of a non-aqueous solvent. In Nakagawa et al., also described above, GTA is combined with an activator, namely an acetic acid ester of sugar or a sugar alcohol, to increase the water solubility and activation of the peroxide bleaching agents through a synergistic effect attained *only* by virtue of the combination. Nakagawa et al., column 1 lines 38-43. The motivation to combine these patents would arise from knowledge that GTA

will by itself react with peroxide to produce peroxyacetic acid to provide tooth whitening, information that is not contained expressly or implicitly in any of the prior patents. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not be based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). As the claimed invention is non-obvious and patentable over these combinations of references, Applicant contends that the obviousness-type double patenting rejections are improper and should be withdrawn.

VII. The Election of Species Requirement

Claims 3, 4, 8, 10, 12, 14, 16, 17, and 18 stand subject to an election of species requirement. Applicant respectfully traverses the election of species requirement. The subject matter of claims 3, 4, 8, 10, 12, 14, 16, 17, and 18 is so interrelated as to make any search unburdensome. Claim 1, which as discussed above is allowable, is generic to the remainder of claims 3-18, which all depend from claim 1.

As separate and distinct grounds for traversing the restriction requirement as applied to the Markush group claims, where the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. MPEP § 803.02. In claim 3, the Markush group is three in number and consists of closely related acetic acid esters of glycerin (glyceryl triacetate, glyceryl diacetate, and glyceryl acetate). Claim 4 has a Markush group numbering seven, all closely related in being sources of peroxide. Claim 14 has only two members in the Markush group, both surfactants, and claim 16 has only three

elements, all chelating agents. These claims contain Markush groups that are *both* sufficiently few in number and closely related so as to require a search and examination of the entire claim as per § 803.02. Additionally, claims 8, which contains carriers, 10, which contains thickening agents, and 12, which contains buffers, have Markush groups in which the group members are closely related and thus can be examined without undue burden.

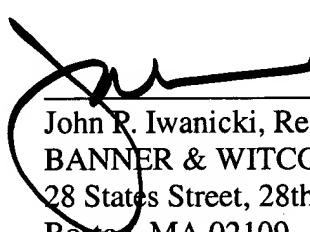
While strenuously traversing the election of species requirement, Applicant elects glyceryl triacetate, polyethylene glycols, carboxypolymethylene, ammonium hydroxide, fluorinated surfactants, EDTA and a flavorant.

VIII. CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicant's attorney would expedite prosecution of the above-identified application, the Examiner is requested to call the undersigned at (617) 227-7111.

Respectfully submitted,

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Version Of Amendments With Markings To Show Changes Made

1. (Twice Amended) A[n oral care] composition [for whitening teeth] comprising:
an orally acceptable, tooth whitening peroxyacetic acid generating mixture including a
source of peroxide and an acetic acid ester of glycerin, wherein the source of peroxide and the
acetic acid ester of glycerin are dispersed within an anhydrous carrier.

3. (Twice Amended) The composition of claim [3] 1 wherein the acetic acid ester of
glycerin is selected from the group consisting of glyceryl triacetate, glycetyl diacetate and
glycetyl acetate.

Please delete claim 7 without prejudice to the filing of any appropriate continuation application.

8. (Amended) The composition of claim [7] 1 wherein the carrier is selected from the
group consisting of glycerin, propylene glycol, polyethylene glycols, chewing gum and gum base
products, floss carriers and floss wax products, oils, waxes and esters.

10. (Amended) The composition of claim 9 wherein the thickening agent is selected from
the group consisting of neutralized carboxymethylene, polyacrylic acid polymers and
copolymers, hydroxypropylcellulose and other cellulose ethers, salts of poly(methyl vinyl ether-
co-maleic anhydride), poly(vinylpyrrolidone), poly(vinylpyrrolidone-co-vinyl acetate), silicon
dioxide, fumed silica, and stearic acid esters[.]